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CENTOCOR ORTHO BIOTECH INC., erroneously served and sued herein as CENTOCOR, INC., and JOHNSON & JOHNSON

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

STEPHEN WENDELL & LISA WENDELL, his wife, for themselves and as successors in interest to MAXX WENDELL, deceased,

Plaintiffs,

v.

JOHNSON & JOHNSON; CENTOCOR, INC.; ABBOTT LABORATORIES; SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICALS USA; GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS USA; PAR PHARMACEUTICALS; MYLAN LABORATORIES, INC.,

Defendants.

Case No. 4:09-cv-04124-CW

DEFENDANT CENTOCOR ORTHO BIOTECH INC.'S AND JOHNSON & JOHNSON'S REPLY IN FURTHER SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Date: February 2, 2012
Time: 2:00 pm
Place: Courtroom 2, 4th Floor
1301 Clay Street
Oakland, CA 94612

Judge: Honorable Claudia Wilken

INTRODUCTION

Plaintiffs fail to raise any genuine issues of material fact and rely on speculation and conjecture to oppose Defendants Centocor Ortho Biotech Inc. ("Centocor") and Johnson & Johnson's ("J&J") motion for summary judgment. The treating and prescribing physician here, Dr. Edward Rich, had independent knowledge of the specific risks at issue from sources other than Centocor. Plaintiffs cannot show that Dr. Rich would have changed his decision to prescribe Remicade if a different warning was provided or if the Black Box Warning was added earlier than May 2006. Centocor provided adequate warnings and precautions regarding the use of Remicade and Plaintiffs cannot point to any specific facts that raise a genuine issue regarding adequacy of the warnings. Because Plaintiffs cannot provide sufficient evidence of causation or raise any issues regarding adequacy of the warnings, summary judgment should be granted to Centocor and J&J.

ARGUMENT

I. PLAINTIFFS FAIL TO PROVIDE EVIDENCE OF OR RAISE ANY GENUINE ISSUES REGARDING CAUSATION

A plaintiff asserting causes of action for failure to warn must prove not only that no warning was provided or that the warning was inadequate, but also that the inadequacy or absence of a warning caused the plaintiff's injury. *Plummer v. Lederle Laboratories*, 819 F.2d 349, 358 (2nd Cir. 1987) (applying California law). In this case, Dr. Rich knew of the risk of malignancies and hepatosplenic T-cell lymphoma ("HSTCL") associated with 6-mercaptopurine ("6-MP") and anti-TNF drugs, including Remicade and Humira, but still prescribed the medication to Maxx Wendell. There is insufficient evidence to create a material dispute that Dr. Rich would have changed Maxx's treatment if he had been given different or additional warnings.

Plaintiffs rely on mischaracterizations of the record attempting to manufacture disputed

issues of fact. First, Plaintiffs allege there is an issue as to when Dr. Rich was aware of the risk of HSTCL associated with the use of Remicade in combination with 6-MP. ECF No. 213 (Plaintiffs' Opposition to Defendants' Summary Judgment Motion) at pp. 11-15. In fact, Dr. Rich testified unequivocally that he was aware of the risk prior to the Black Box Warning regarding HSTCL. ECF No. 205, Declaration of Michelle Childers ("Childers Decl.") ¶ 2, Ex. 1 (Transcript of Deposition of Dr. Edward J. Rich ("Rich Dep.")) at 205:11-23, 200:20-202:22, 203:18-207:5, 214:23-215:22. He further testified that he believed that the risk applied to all anti-TNF drugs, including Remicade and Humira, warned his patients of the risk, and prescribed anti-TNF drugs with knowledge of the risk. *Id*. at 137:21-138:5, 264:21-265:19, 122:22-123:10. Second, Plaintiffs argue that Dr. Rich prescribed Humira instead of Remicade in November 2006 because Remicade had a Black Box Warning regarding HSTCL and Humira did not. ECF No. 213 at pp. 14-15. However, this argument already was rejected by the Court in its December 15, 2011 Order Granting Motions for Summary Judgment. ECF No. 204 (Order Granting Summary Judgment Motions) at pp. 7-10, 14 ("there is insufficient evidence for a jury to infer that Dr. Rich ceased treating Maxx with Remicade because of the May 2006 Black Box Warning regarding the risk of lymphoma associated with therapy combining Remicade and 6-MP."). Because Plaintiffs failed to provide evidence of causation, Centocor and J&J's summary judgment motion should be granted.

A. Dr. Rich Had Independent Knowledge of the Risk of HSTCL in 2005

There is no genuine dispute that Dr. Rich already was aware of the risk of HSTCL prior to the May 2006 Black Box Warning for Remicade. Plaintiffs argue that Dr. Rich's testimony regarding his knowledge of HSTCL is "already suspect" and "defendants' assertion that they were not aware of a 'safety signal' until April, 2006, if credited, further undermines the doctor's credibility about when he knew about the risk." ECF No. 213 at p. 11. This is not true. Dr. Rich

did not testify that his knowledge of the risk of HSTCL was due to Centocor or the United States Food and Drug Administration ("FDA"). And making credibility arguments is not enough to avoid summary judgment. *See Plummer*, 819 F.2d at 358 ("It may be true that [the prescribing doctor] was an interested witness, but his was the only testimony on the issue of proximate cause. Even if the jury failed to credit him, [the plaintiff] has not proven an essential element of his case.").

Dr. Rich received information on medications from multiple sources, including meetings, other professionals in the field, articles and occasional meetings with pharmaceutical representatives. ECF No. 205, Childers Decl. ¶ 2, Ex. 1 (Rich Dep.) at 192:7-14. Dr. Rich testified repeatedly, not just once or twice, that he knew of the risk of HSTCL before May 2006. *Id.* at 205:11-23, 200:20-202:22, 203:18-207:5, 214:23-215:22. Specifically, Dr. Rich testified that:

> Q. Okay. And when you received that information, Doctor, did you continue, after that point, to prescribe Remicade in combination with 6-MP for any of your patients?
>
> A. So I knew this information before the black box warning or messaging from the patient (verbatim). I was aware of literature as it evolved. This is a very important part of our treatment. And was aware from many sources when cases first got -- were first reported, came to my attention. I believe that was sometime in 2005. I can't tell you when. And your question, then, to repeat it, is what?
>
> Q. Well, let's break it down into two things. When you first started getting information, did you have a comprehensive analysis like this, that there were these cases that had been reported to the FDA of hepatosplenic T-cell lymphoma in patients who were receiving Remicade concomitantly with 6-mercaptopurine or azathioprine?
>
> A. So --
>
> THE WITNESS: I can't remember exactly the time course of what I learned and where. At some point I became aware of cases of hepatocellular T-cell lymphoma in young males on combination therapy of Remicade and immunosuppressive therapy. And at some point, there was a report. I can't -- I don't remember if it was first at a meeting -- I didn't attend the meeting, if that was true -- or if it was

> an abstract or if it was just a case report of a number of patients. The number in my head is something like six patients with this rare or uncommon lymphoma. And then at some point there was an article on this, I believe. At first it might have been a report and then an article, but I can't exactly be sure. And when the article came out it was six to eight patients, and this was before the black box warning came out.

Id. at 205:11-207:5. Dr. Rich knew of the information before the Black Box Warning and learned of the specific risk from "many sources" *Id*. He followed the literature as it evolved because it was a very important part of treatment of his pediatric patients. *Id*.

Plaintiffs focus on a section of Dr. Rich's testimony attempting to create an issue regarding Dr. Rich's knowledge of HSTCL prior to the Black Box Warning. ECF No. 213 at pp. 11-15. Plaintiffs argue that "Dr. Rich remembers finding out about the risk from a report of multiple ***cases***" – but this misstates Dr. Rich's testimony. ECF No. 213 at pp. 12-13. Dr. Rich's testimony does not refer to a single report but instead refers to "many sources" and references the fact that he "was aware of the literature as it evolved." ECF No. 205, Childers Decl. ¶ 2, Ex. 1 (Rich Dep.) at 205:11-207:5. This is clear from his statements that "[a]t some point I became aware of cases of [HSTCL]…And at some point, there was a report…And then at some point there was an article on this." *Id*. at 206:12-207:5.

Plaintiffs also focus on Dr. Rich's testimony that "when the article came out it was six to eight patients, and this was before the black box warning came out." ECF No. 213 at p. 13. Plaintiffs argue that Dr. Rich was referring to "an article by Mackey, *et al* in ***2007*** which noted that '[a]s of ***October 5, 2006***, the FDA's Adverse Event Reporting System has received ***8 cases*** of HSTCL.'" *Id*. However, Plaintiffs chose not to ask Dr. Rich about this article at his deposition. In any event, Dr. Rich expressly testified to learning abut a progression of information and then, "at some point" there was an article. Dr. Rich's testimony is consistent with knowing about the risk in late 2005 and a paper on the subject appearing in 2007. It is pure speculation on the part

of Plaintiffs that Dr. Rich was referring to the specific article attached to Plaintiffs' papers. Moreover, there are multiple other instances in Dr. Rich's testimony in which he said he knew of the risk of HSTCL before the Centocor Black Box Warning. ECF No. 205, Childers Decl. ¶ 2, Ex. 1 (Rich Dep.) at 200:20-202:22, 214:23-215:22.

It is natural that Dr. Rich would remember the specific time he first learned of the risk of HSTCL. He testified that the use of combination therapy was "a very important part of our treatment." *Id*. at 205:18-19. He also testified that HSTCL is a rare form of cancer that runs an aggressive disease course and is usually fatal. *Id*. at 212:14-213:1. Dr. Rich would have remembered when he first learned of the risk because it was "important information and – an information I would have passed on to my patients, always." *Id*. at 213:2-10.

Credibility attacks on Dr. Rich and convoluted questioning of his testimony do not satisfy Plaintiffs' burden of proximate causation. Plaintiffs have no evidence, in the form of testimony by Dr. Rich or otherwise, that their proposed warning would have altered Maxx's treatment. *See, e.g.*, ECF No. 204 at pp. 15-17. Summary judgment should be granted because Plaintiffs cannot meet their burden of proving that the alleged inadequacy or absence of the warning caused the Plaintiffs' injury. *Plummer*, 819 F.2d at 358; *see Ramirez v. Plough, Inc.*, 6 Cal. 4th 539, 556, 863 P.2d 167, 177 (Cal. 1993) (requiring "causal connection between the representations or omissions that accompanied the product and plaintiff's injury"); *Lord v. Sigueiros*, No. 040243, 2006 WL 1510408, at *3 (Cal.Super.Ct. Apr. 26, 2006); *see also Mack v. Amerisourcebergen Drug Corp.*, No. 08-688, 2009 WL 4342513 (D. Md. Nov. 24, 2009), *aff'd*, 2011 WL 1584341 (4th Cir. April 16, 2011).

B. Dr. Rich Did Not Switch Maxx's Prescription Because of Remicade's Black Box Warning

Plaintiffs rely on a mischaracterization of Dr. Rich's testimony to allege that the Black

Box Warning on Remicade affected his decision in November 2006 to prescribe Humira for Maxx. ECF No. 213 at pp. 3, 14. Plaintiffs also made a similar argument in Opposition to the other Defendants' Summary Judgment Motions. ECF No. 204 at pp. 16-17. The argument was rejected by the Court in its Order Granting Motions for Summary Judgment. *Id*. It should be rejected again here.

Dr. Rich testified that Black Box Warnings were not the primary driver for his decisions regarding medication. *Id*. at 219:23-220:15. He also testified that labeling on medication is "sometimes something I rely on when making decisions on drug use for patients" but he also "use[s] medications without looking at the drug labeling." *Id*. at 190:16-191:13. Dr. Rich uses labeling for medications that he is less familiar with. *Id*. Dr. Rich first began prescribing Remicade in the year 2000. *Id*. at 118:2-7. There is no support for Plaintiffs' contention that the Black Box Warning was the reason Dr. Rich prescribed Humira in November 2006 instead of Remicade.

Dr. Rich did not decide to switch Maxx to Humira from Remicade in November 2006 because of Remicade's May 2006 Black Box Warning. Dr. Rich testified that he first began considering whether to discontinue Remicade for Maxx in November 2005. ECF No. 205, Childers Decl. ¶ 2, Ex. 1 (Rich Dep.) at 170:24-173:8. That discussion was over six months before the Black Box Warning was added to Remicade's labeling. Dr. Rich explained that he typically discussed switching from Remicade to Humira with high school and college-aged patients because Humira could be injected at home, while Remicade required a two- to three-hour infusion at Dr. Rich's clinic. *Id*. at 174:1-22; 266:21-267:23. Maxx was 19 years old in November 2005.

Plaintiffs cite one quote by Dr. Rich, and take it completely out of context, to support their argument that Dr. Rich switched Maxx to Humira in November 2006 because of Remicade's

Black Box Warning. ECF No. 213 at p. 14. The questioning prior to Plaintiffs' citation is as follows:

> Q. If one drug has a black box warning about a rare, aggressive, and fatal cancer and the other drug does not --
>
> A. Uh-huh.
>
> Q. -- would that inform your decision about which drug to recommend to your patient?
>
> THE WITNESS: I don't think the black box would have been a primary driving point in the use of medicine, just as FDA indication or not is not a driving point, as FDA doesn't indicate very much of anything for pediatrics.

ECF No. 205, Childers Decl. ¶ 2, Ex. 1 (Rich Dep.) at 220:3-15. Plaintiffs' cite Dr. Rich's testimony that:

> The occurrence of hepatosplenic T-cell lymphoma and the information and knowledge about that would have been part of the many things that would have gone into my thinking on how to use these – these medications and my discussion with the patients on how to use these drugs.

ECF No. 213 at pp. 14-15. However, that statement does not support Plaintiffs' position. Dr. Rich did not testify that the May 2006 Black Box Warning affected his decision to recommend Humira instead of Remicade. Rather, this testimony is in line with Dr. Rich's testimony regarding all of the factors he considered when making treatment suggestions for patients on a case by case basis. ECF No. 205, Childers Decl. ¶ 2, Ex. 1 (Rich Dep.) at 259:11-260:4, 265:4-19.

Further, Dr. Rich understood that both Remicade and Humira were anti-TNF drugs and there was an increased risk of HSTCL associated with anti-TNF drugs when used in combination with immunosuppressants, such as 6-MP. *Id*. at 137:21-138:5, 264:21-265:19. Dr. Rich testified that when he discussed Humira with Maxx and his parents:

> We would have talked about the reasons for using the medicine, the benefits of the medicine, the goals of the use of the medicine, the potential adverse side effects of the medicine. And we would have discussed -- my usual line of increased risk of serious infection and malignancies, and at the point where this patient was being treated, the specific increased risk of hepatosplenic T-cell lymphoma would have

been discussed.

Id. at 265:4-19. So, even though Humira did not include a Black Box Warning regarding HSTCL at that time, Dr. Rich considered HSTCL a risk when he prescribed Humira for Maxx in November 2006. Thus, Plaintiffs cannot point to any evidence that a new or different warning on Remicade, or other anti-TNF drugs, would have made a difference in Maxx's treatment. As this Court already held, this evidence requires that summary judgment be granted because Plaintiffs have no evidence of causation. ECF No. 204; *see also Plummer*, 819 F.2d at 359.

II. NO GENUINE ISSUE REGARDING WHETHER THE WARNINGS ON REMICADE WERE INADEQUATE OR ABSENT

Plaintiffs fail to cite any specific evidence or legal authority that raise a genuine issue as to whether the Remicade labeling and warnings were inadequate or absent. Plaintiffs must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). In opposition to Defendants' motion, Plaintiffs speculate that the Remicade warnings were inadequate. ECF No. 213 at pp. 5-9. Plaintiffs spill a lot of ink attempting to raise doubts regarding the date of the safety signal regarding HSTCL, but fail to cite to any actual evidence that supports their position. *Id*. at pp. 9-10.

In fact, Plaintiffs' contention that there "was only ***one case report*** in the medical literature of a ***single case*** of [HSTCL] in a young male on concomitant Remicade and immunosuppression ***prior to the black box warning***" (ECF No. 213 at p. 12 (emphasis in original)) is directly in conflict with Plaintiffs' speculation regarding the April 2006 safety signal for HSTCL. A single report of a single case demonstrates the futility of Plaintiffs' questioning the date of the safety signal. If there was "only one case report in the medical literature of a single case" prior to the Black Box Warning, how could Remicade's warnings be inadequate? Centocor provided

adequate warnings to physicians about any known or reasonably knowable side effects of Remicade and therefore met its duty to warn. *Motus v. Pfizer, Inc.*, 196 F.Supp.2d 984, 991 (C.D. Cal. 2001), *aff'd sub nom. Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004).

California follows the learned intermediary doctrine, which requires that in the case of prescription medicines, the duty to warn "runs to the physician, not to the patient." *Carlin v. The Superior Court of Sutter County*, 13 Cal.4th 1104, 1116, 56 Cal.Rptr.2d 162, 920 P.2d 1347 (1996) (citations omitted).

Plaintiffs' assertions that they require additional discovery regarding the November 2005 Supplemental Biologics License Application ["sBLA"] and the date of the safety signal are further attempts to manufacture a factual dispute. On April 19, 2011, Defendants produced relevant and responsive documents from the Remicade Investigational New Drug Application(s) ("IND"), Biologics License Application ("BLA"), and the sBLAs, including the November 2005 sBLA. Yet, Plaintiffs do not cite any evidence from the sBLA that supports their contention that the date of the safety signal is in dispute. Also, Centocor's Response to Plaintiffs' Interrogatory No. 9, which was served on August 25, 2010, is as follows:

> INTERROGATORY NO. 9: Please identify the date and/or month and year on or in which you initially became aware of and/or learned of information regarding the potential association between the use of Remicade® either singly or in combination with immunomodulating drugs including the purines azathioprine and 6-mercaptopurine and hepatosplenic T-cell lymphoma (HSTCL).
>
> Answer: Centocor objects to this interrogatory as vague, ambiguous and confusing, and as overly broad and unduly burdensome. Subject to the foregoing general and specific objections, and as best it understands this interrogatory, Centocor responds that it became aware of this safety information on or about April 2006.

Declaration of Michelle A. Childers In Support of Defendants Centocor Ortho Biotech, Inc. and Johnson & Johnson's Reply in Support of Motion for Summary Judgment ("Second Childers Decl.") ¶ 2, Ex. 1 (Centocor Interrogatory Responses, served August 25, 2010). To the extent

Plaintiffs claim that April 2006 date for the safety signal is newly discovered, such a claim cannot be supported. Centocor consistently stated throughout this case that it became aware of the risk of HSTCL in April 2006. The alleged need for additional discovery is no excuse for Plaintiffs' failure to review discovery provided more than one year ago or their failure to rely on actual evidence.

In addition, Plaintiffs fail to provide the required affidavits and reasoning as to how the additional discovery would assist in opposing summary judgment. To justify a continuance or denial of summary judgment under Fed. R. Civ. P. 56(d), when facts are unavailable to a nonmovant, a party must satisfy the following requirements:

> (1) it has set forth in affidavit form the specific facts it hopes to elicit through further discovery; (2) the facts sought exist; and (3) the sought after facts are essential to oppose summary judgment.

Family Home and Finance Center v. Federal Home Loan Mortgage Corporation, 525 F.3d 822, 827 (9th Cir. 2008). Plaintiffs failed to submit an affidavit, and other than speculation regarding the date of the safety signal, have not stated what evidence they hope to develop. Further, Plaintiffs neglected to suggest how the unidentified evidence will help in opposing summary judgment. Plaintiffs have not satisfied the requirements for denial of summary judgment due to additional discovery needs.

Reliance on speculation is insufficient to defeat summary judgment. *See, e.g., Hernandez v. Spacelabs Med. Inc.*, 343 F.3d 1107, 1112 (9th Cir. 2003) (non-moving party "cannot defeat summary judgment with . . . unsupported conjecture or conclusory statements"); *R.W. Beck & Assocs. v. City and Borough of Sitka*, 27 F.3d 1475 (9th Cir. 1994) ("Arguments based on conjecture or speculation are insufficient to raise a genuine issue of material fact"). Because Plaintiffs fail to cite any actual evidence that raises a genuine issue, summary judgment should be granted.

A. Remicade's Precautions and Warnings Regarding Lymphoma Were Not Misleading or Inadequate

Plaintiffs argue that the Precautions and Warnings regarding lymphoma in Remicade's labeling were misleading and inadequate. ECF No. 213 at pp. 7-9. Remicade's labeling included information regarding lymphoma and malignancies from the time it was first approved in August 1998. ECF No. 205, Jones Aff. at ¶¶ 7-10, 13. Contrary to Plaintiffs' assertion, in light of Dr. Rich's testimony that he was aware of the risk since late 2005, the Remicade Precautions, Warnings, and Adverse Event information constituted an adequate warning of the risk of malignancies and lymphoma. *See Motus*, 196 F.Supp.2d at 991; *see also Plummer*, 819 F.2d at 359 (citation omitted) ("no one needs notice of that which he already knows."). In addition, "[u]nder California law, interpretation of the adequacy of the written language of a warning is a question of law which can be decided on summary judgment." *Dash v. Roche Labs.*, 74 F.3d 1245, 1996 WL 12588 (9th Cir. (Cal.) Jan. 11, 1996) (*citing Temple v. Velcro USA, Inc.*, 148 Cal.App.3d 1090, 1094-1095 (1983)).

The Remicade labeling did not include reassuring statements regarding malignancies and lymphomas. Therefore, it is different from the labeling at issue in *Rowatt v. Wyeth*, 244 P.3d 765 (Nev. 2010), *cert. denied sub nom Wyeth v. Scofield*, 131 S. Ct. 3028 (2011). The warnings in *Rowatt* were inadequate because they "stated the relationship between progestrin and breast cancer is unknown, that the majority of studies show no increase in breast cancer risk, and that the rate breast cancer that showed up in Wyeth's human study did 'not exceed that expected in the general population.'" *Id*. at 784. However, Remicade's labeling did not compare the risk to the general population. For example, as far back as the August 1998 labeling, the Adverse Reactions section stated: "The lymphomas reported occurred in patients with a long duration of disease and chronic exposure to immunosuppressant therapies, a population at greater risk for development of

malignancy." ECF No. 205, Jones Aff. at ¶ 7. The risk of malignancy was compared to specific types of patients. The terms malignancy and lymphoma were not used in reassuring statements on Remicade's labeling. *Compare Rowatt*, 244 P.3d at 784.

Plaintiffs allege that Dr. Rich testified that Remicade's labeling suggested that there was not an increased risk of malignancies associated with the drug itself as distinct from the underlying disease. ECF No. 213 at p. 8. This claim ignores Dr. Rich's actual warnings to his patients. Dr. Rich testified as follows:

> Q. And then the last sentence there indicates, "The observed rates and incidences were similar to those expected for the population studied." What does that mean?
>
> A. That suggests there is not an increased rate or incidence --
>
> Q. Associated with Remicade?
>
> A. That's what it suggests.
>
> Q. Okay. And that's what you would have thought your patient at the time?
>
> THE WITNESS: I thought my -- I thought my patients what I said before. I would have thought my patient that there was a low -- an increased -- a low but nonzero increased risk of malignancies in the use of immunosuppressives and anti-TNF drugs, including Remicade.
>
> * * *
>
> Q. Doctor, does that last line indicate that the observed rates and incidences in the treated population are no different than what would be -- expected in the population?
>
> A. That's what the FDA report says --
>
> THE WITNESS: "Observed rates and incidences were similar to those expected for the population studied."
>
> * * *
>
> Q. Is that consistent with what you were describing to your patients as a low but nonzero risk of malignancy?
>
> THE WITNESS: I stated to my patients that there was a low but nonzero increased risk of serious infections and malignancies using immunosuppressives

and anti-TNF drugs.

ECF No. 205, Childers Decl. ¶ 2, Ex. 1 (Rich Dep.) at 134:9-137:19. Dr. Rich's testimony does not raise any issues regarding the alleged inadequacy of Remicade's labeling.

III. NO BASIS EXISTS FOR ANY CLAIM AGAINST CENTOCOR'S PARENT, JOHNSON & JOHNSON

Plaintiffs fail to raise any genuine issue of material fact regarding J&J's possible liability. Instead, Plaintiffs attempt to manufacture an issue by alleging there was no discovery on the relationship between Centocor and J&J. This issue is not genuine. In Centocor and Johnson and Johnsons' Answer to Plaintiffs' Fourth Amended Complaint, filed on April 26, 2011, J&J "expressly denie[d] any involvement with Remicade." ECF No. 166 at paras. 2, 84. In addition, J&J provided interrogatory responses to Plaintiff that further stated J&J's contention that it is not involved in the research, development, marketing, or manufacture of Remicade. Second Childers Decl. ¶ 3, Ex. 2 (J&J Interrogatory Responses, served August 25, 2010). Plaintiffs already sought discovery and failed to find any evidence of J&J's involvement with Remicade. Summary judgment of all clams against J&J should be granted.

Plaintiffs also cannot offer any legal basis upon which J&J is liable. *See, e.g., United States v. Bestfoods*, 524 U.S. 51, 55 (1998) (parent corporation actively participating in and exercising control over subsidiary's operations, without more, is not sufficient to hold parent liable). Even if additional discovery was allowed on the relationship between J&J and Centocor, Plaintiffs do not explain how that discovery would lead to liability for J&J. Because Plaintiffs fail to cite any legal authority for holding J&J liable, the request for additional discovery on the relationship is a non-issue and summary judgment should be granted.

CONCLUSION

It is undisputable that Dr. Rich knew of the possible risk of HSTCL before Centocor's Black Box Warning and did not rely on any information from Centocor to make his prescribing decisions. Dr. Rich also continued to prescribe anti-TNF drugs in combination with 6-MP even after the May 2006 Black Box Warning. In addition, because Dr. Rich had knowledge of the risk at issue here and acted as a "learned intermediary," Plaintiffs cannot show that Centocor's allegedly inadequate warning or lack of warning was the proximate cause of their injuries.

All counts against J&J must be dismissed because it is not involved with Remicade and is a separate entity from and has no domination over Centocor. Plaintiffs fail to provide any legal authority or evidence to the contrary.

For the reasons discussed in Defendants' Motion for Summary Judgment (ECF No. 205) and herein, the Court should grant Centocor and J&J summary judgment on the Plaintiffs' Third and Fourth counts of the FAC.

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